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Re: Docket Number 98N-0359; Program Priorities in the Center for Food Safety and Applied Nutrition for the Year 2000

On behalf of the Food, Drug, and Cosmetic Packaging Materials Committee of The Society of the Plastics Industry, Inc. (SPI), we hereby respectfully submit these comments concerning the program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for the year 2000.^{1/} Our comments focus on the premarket review of food additives program, particularly as it relates to the consideration of food contact substances, sometimes called "indirect additives." More specifically, we are recommending priority consideration regarding two aspects of food contact substance premarket review in the year 2000.

^{1/} The Society of the Plastics Industry, Inc. is the trade association representing the fourth-largest manufacturing industry in the United States. SPI's 2,000 members represent the entire plastics industry supply chain, including processors, machinery and equipment manufacturers and raw material suppliers. The U.S. plastics industry employs 1.3 million workers and provides \$274 billion in annual shipments. Founded in 1937, SPI is the voice of the plastics industry. The Food, Drug, and Cosmetic Packaging Materials Committee is composed of representatives of SPI member companies with special interest and expertise in packaging materials for drugs and other FDA-regulated products.

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First, with respect to the pending implementation of the food contact notification (FCN) program, we encourage CFSAN to fully implement the program under the provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA) so that it will function, as envisioned, as a replacement in substantial part for the petition process for food-contact materials. It remains our belief that full implementation will ultimately, if not immediately, result in a significant conservation of resources which the Agency can then devote to other programs that have a greater bearing on public health, *e.g.*, the food safety initiative.

The second area where we recommend CFSAN focus or reorient attention is in improving petition review time while petitions are still pending; later, when the notification program is in full place, the concepts suggested here could facilitate notification reviews as well as the review time of food-contact petitions. It is now very clear that the review area that needs the most concentrated attention if time savings are to be realized is in the time used for toxicological reviews. *See* the new report entitled "Resource Evaluation of the FDA Food Additive Petition Process," prepared by The Research Triangle Institute (RTI) at the behest of the Department of Health and Human Services.^{2/} Since exposures are generally low where food contact substances are concerned, it would appear that the substantial delays now suffered in waiting for action on such petitions must be due to process delays rather than substantive ones, and that the area which could benefit most from process changes should be that involving toxicology review.

On its face, the RTI report implicitly indicates that the toxicology division either spends an inordinate amount of time in reviewing petitions, or suffers so many interruptions in its reviews that the appearance of the spending of inordinate time is presented. Our experience has led us to conclude that the system would be improved significantly, and new incentives would exist for more efficient action, if the Center's Division of Health Effects and Evaluation (DHEE) adopted and adhered to a clear-cut petition classification and tracking system designed to limit bottlenecks that currently hold up review of "easy cases" when more difficult situations come up and are "first in line," so to speak. To the best of our knowledge, currently there is no standard operating procedure for how petitions are distributed within DHEE, although it does seem that there is some laudable effort to allocate particular categories of petitions to the same group of toxicologists. To improve the process, and the confidence of the public and the rest of the Agency in it, we urge that consideration be given to instituting a screening and tracking system for food-contact petitions (and perhaps all others if the Agency considers it advisable) in DHEE, and designating a group of toxicologists whose first priority should be to review food-contact petitions in a timely manner.

Specifically, we propose that a DHEE staff member be assigned to the task of routinely performing a cursory examination of petitions to categorize petitions based on type (*e.g.*, direct additive petitions, food-contact petitions, etc.) so that, for example, food-contact petitions will be

^{2/} This report can be found on FDA's website at <http://vm.cfsan.fda.gov/~dsm/opa-rtie.html>.

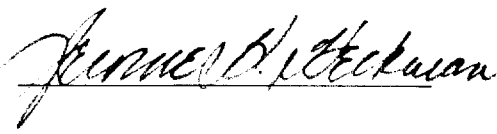
assigned to a specific group for evaluation. Moreover, we recommend that, in keeping with the philosophy underlying the very successful Special Project Team operation, DHEE prioritize petitions involving low dietary exposure so that they are cleared rapidly in the absence of any unusual circumstances. Separating food-contact petitions from other types of petitions is a sensible approach, since the majority of food-contact petitions involve very low dietary exposure, ergo low risk, and, consequently, do not require heavy time-consuming toxicology review. Further, completing a timely review of the simpler, low exposure petitions would be advantageous to CFSAN as a whole, because it would improve the Agency's overall review time record, and improve government-industry relations without delimiting public health protection in any way.

Finally, we recommend that a "transparent" tracking system be put into place so that a petitioner can easily ascertain the status of all phases of toxicology review, including how long the reviewer has had the petition and when the review is expected to be completed. Such a system also would improve relations with industry and create additional desirable accountability within DHEE.

SPI appreciates this opportunity to comment on the program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for the year 2000 and would be pleased to supply further information concerning these recommendations if any is needed or desired.

Respectfully submitted,

THE SOCIETY OF THE PLASTICS
INDUSTRY, INC.

By: 

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